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10/757,667	01/14/2004	Anthony John Kinney	BB1071 US DIV2	7292

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WILMINGTON, DE 19805

EXAMINER

KUMAR, VINOD

ART UNIT	PAPER NUMBER
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1638

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/757,667

Applicant(s)

KINNEY ET AL.

Examiner

Vinod Kumar

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 10 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11/24/2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 01/14/04; 07/13/06.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

DETAILED ACTION

Election/Restriction

1. The Office acknowledges the receipt of Applicant's remarks filed on October 10, 2006 regarding the claim Amendment filed on January 14, 2004. Accordingly, claims 1-21 are cancelled as requested by Applicants and restriction requirement mailed on October 4, 2006 is WITHDRAWN. Claims 22-24 are pending and are being examined in the instant application. Applicants are advised that if any claims including all the limitations of an allowable claim examined here are presented in a continuation or divisional application, such claims may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Information Disclosure Statement

2. Initialed and dated copies of Applicant's IDS form 1449 filed on July 13, 2006 and January 14, 2004 are attached to the instant Office action.

Specification

The disclosure is objected to because of the following informalities:

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3. Page 22, line 25 does not contain SEQ ID listed with the nucleotide sequence. The sequence must be referred to by its sequence identifier as required by 37 CFR 1.821. If the sequences appearing in the specification do not have sequence ID numbers assigned to them, then an amendment to the sequence listing will be required as well. There must not be any new matter submitted, therefore it is important to be careful to include only the sequences that are already disclosed in the current specification. Failure to correct the deficiency will be held a non-responsive to this Office action.

4. Brief description to drawings must identify all the labels in Figures 5 and 7. Appropriate action/corrections are required.

Claim Objections

5. Claims 22-24 are objected to because of the following informalities:

In claims 22-23, part (a) (i), and claim 24, line 5, it is suggested to replace "encoding" with --comprising--. Nucleic acid does not encode a promoter, which is also a nucleic acid.

In claim 22, line 15, and claim 23, line 18, replace "soybeans" with --soybean seeds--.

In claim 24, line 3, replace "a" after "in" and before "soybean" with --the--.

In claim 24, line 11, replace "a" at the end of line with --the--.

Appropriate action/corrections are required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 22-24 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 6-9, 12, and 14-20 of U.S. Patent No. 6,703,544 ('544) and in view of Kinney et al. (U.S. Patent No. 6,703,544, issued March 9, 2004). Although the conflicting claims are not identical, they are not patentably distinct from each other because the soybean seeds with reduced levels of soybean seed storage proteins and a method of producing said seeds as claimed by Patent '544 involves the transformation of plants with a nucleic acid fragment (sense or antisense orientation with respect to promoter) encoding all or a portion of a soybean or

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non-soybean seed storage protein. The method steps of instant claims 22-23 to obtain instantly claimed food comprising soybean seeds with reduced levels of seed storage protein are encompassed by the method steps of claims 1-4, 6-9 and 12 of Patent '544. The method steps required to obtain reduced levels of soybean glycinin and β -conglycinin of claim 2 of Patent '544 encompass the method steps of instant claims 23 to obtain instantly claimed food comprising soybean seeds with reduced levels of seed storage protein. Transgenic plant and transgenic soybean seeds of claims 14 and 16 of patent '544 are encompassed by the transgenic soybean plants and seeds used to prepare food of instant claims 22. Transgenic plant and transgenic soybean seeds of claims 15 and 17 of patent '544 are encompassed by the transgenic soybean plants and seeds used to prepare food of instant claims 23. Transgenic plant and transgenic soybean seeds of claims 18 and 19 of patent '544 are encompassed by the transgenic soybean plants and seeds used to prepare food of instant claims 24. The chimeric gene of claim 20 of patent '544 is encompassed by the chimeric gene used to prepare food of instant claims 24.

US patent '544 does not claim that said transgenic soybean seeds with reduced levels of seed storage proteins, such as glycinin and β -conglycinin can be used in food preparation.

However, US patent '544 teaches that soybean seeds with reduced levels of seed storage proteins, such as glycinin and β -conglycinin, can be used to improve physical characteristics of soybean derived food products. See in particular, 2nd column.

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It would have been prima facie obvious to one of ordinary skill in the art at the time claimed invention was made to use the patented method of reducing any soybean seed storage protein including glycinin and/or β -conglycinin to prepare soybean seed derived food products, using any appropriate food processing method. One of ordinary skill would have been motivated to use said soybean transgenic seeds with reduced levels of seed storage proteins in the preparation of food, given the economic importance of improving the quality of soybean derived food products as asserted by US patent '544.

This is a non-provisional obviousness-double patenting rejection because conflicting claims have been patented.

7. Claims 22-24 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent No. 6,362,399 ('399) and in view of Kinney et al. (U.S. Patent No. 6,362,399, issued March 26, 2002). Although the conflicting claims are not identical, they are not patentably distinct from each other because the soybean seeds or plants with reduced levels of soybean seed storage proteins as claimed by Patent '399 involves the transformation of soybean plants with a chimeric gene comprising at least a portion of glycinin or a beta conglycinin gene. Transgenic plant and transgenic soybean seeds of claims 1 and 2 of patent '399 are encompassed by the transgenic soybean plants and seeds used to prepare food of instant claims 22-24.

US patent '399 does not claim that said transgenic soybean seeds with reduced levels of seed storage proteins, such as glycinin and β -conglycinin can be used in food

preparation. Furthermore, US patent '399 does not claim that transgenic soybean seeds were produced by sense or antisense based gene suppression of endogenous soybean seed storage proteins, such as glycinins and β -conglycinins.

However, US patent '399 teaches that soybean seeds with reduced levels of seed storage proteins, such as glycinin and β -conglycinin, can be used to improve physical characteristics of soybean derived food products. See in particular, 2nd column. US patent '399 also teaches that sense or antisense based method of suppressing gene expression can be used to down-regulate the expression of soybean seed storage proteins. See columns 3-4.

It would have been prima facie obvious to one of ordinary skill in the art at the time claimed invention was made to use the patented transgenic soybean seeds having the reduced quantity of glycinin and/or β -conglycinin, obtained by using any gene suppression based technique, including the antisense or sense gene suppression based approach of down-regulating endogenous soybean seed storage proteins as taught in the Patent '399. One of ordinary skill would have been motivated to use said soybean transgenic seeds with reduced levels of seed storage proteins in the preparation of food, given the economic importance of improving the quality of soybean derived food products as asserted by US patent '399.

This is a non-provisional obviousness-double patenting rejection because conflicting claims have been patented.

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35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claim 24 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim 24 reads on food prepared naturally from soybean seeds, which are obtained naturally from a soybean plant comprising in its genome a naturally occurring chimeric gene for reducing the amount of at least one soybean seed storage protein gene per se. A chimeric expressible gene can be naturally produced through naturally occurring non-homologous recombination between the gene sequences of a plant genome that are not related. Food prepared from soybean seeds obtained from soybean plants comprising chimeric genes encoding seed storage protein glycinin or β -conglycinin, as claimed in claim 24 have the same characteristics as those found naturally in the genome or as cellular precursors thereof and therefore does not constitute patentable subject matter. See *American Wood v. Fiber Disintegrating Co.*, 90 U.S. 566 (1974), *American Fruit Growers v. Brodget Co.*, 283 U.S. 2 (1931), *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 33 U.S. 127 (1948), *Diamond v. Chakrabarty*, 206 USPQ 193 (1980).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 22-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 22-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in their recitation "under conditions that results in expression of the chimeric gene", which is confusing, since it is unclear which "conditions" are being referred to. It is also unclear which types of "conditions" are encompassed and which are not? It is unclear what is intended?

Claim 24 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in its recitation "sufficient" which is confusing since metes and bounds of the recitation "sufficient" are unclear as it is not defined.

Claim 24 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in its recitation "reduce" which is confusing since the recitation "reduce" is a relative term and lacks comparative basis.

Claims 24 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in its recitation "soybean seeds obtained from a soybean plant ", which is confusing, since it is unclear whether the seed comprises the chimeric gene. It is suggested that the recitation "comprising" in line 2, after "plant" and before "in" be replaced with --, wherein the seeds comprise--.

Claim 24 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in its recitation "reducing the amount of at least one soybean seed storage protein in a

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soybean plant", which is confusing since it is unclear how seed storage protein that is expressed only in seeds is reduced in the entire plant. It is suggested to replace "plant" with --seed--.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 22-25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a food prepared from soybean seeds having reduced quantity of glycinin and/or β -conglycinin, wherein said seeds are prepared by a method comprising antisense or sense suppression of endogenous seed glycinin and/or β -conglycinin gene expression, comprising transformation of soybean seeds with a chimeric gene which comprises a nucleic acid fragment derived from soybean glycinin or β -conglycinin coding sequence, does not reasonably provide enablement for reducing the levels of (a) soybean glycinin or β -conglycinin seed storage proteins (b) any soybean seed storage protein, comprising transformation of soybean seed with a chimeric gene which comprises a nucleic acid fragment derived from any soybean seed storage protein coding region. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

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Claims are broadly drawn to food prepared from soybean seeds having a reduced quantity of soybean seed storage protein prepared by a method comprising constructing a chimeric gene comprising a promoter operably linked to a nucleic acid fragment encoding all or a portion of a soybean seed storage protein or seed storage protein of any plant species placed in sense or antisense orientation, or wherein said soybean seed storage protein is glycinin or β -conglycinin.

Specification teaches transgenic soybean seed embryos transformed with a DNA construct comprising expression of sense or antisense fragments of nucleic acid fragments derived from a nucleotide sequence encoding soybean β -conglycinin. The transgenic soybean embryos exhibited reduced levels of β -conglycinins. No transgenic soybean embryos or seeds with reduced levels of glycinin using sense or antisense based cosuppression are described. See Examples 1-4.

Claims 22-23 are directed to food prepared by a method of reducing the levels of any soybean seed storage protein using antisense or sense nucleic acid fragment encoding all or a portion of any soybean seed storage protein. Specification provides guidance on a method of reducing soybean glycinin or β -conglycinin seed storage proteins using sense or antisense based cosuppression comprising nucleic acid fragments derived from glycinin or β -conglycinin coding region. Specification does not provide guidance on a method using sense or antisense based cosuppression using a nucleic acid fragment encoding *any* soybean seed storage protein or fragment thereof in down-regulating *any* soybean seed storage protein including glycinin or β -conglycinin.

Antisense suppression of gene expression is highly unpredictable, and the prior art suggests that success depends on the % identity between the sequence of the antisense construct and the target gene sequence. See Elomaa et al. (Molecular Breeding, 2:41-50, 1996; paragraph bridging pages 47-48, in particular). Further, Colliver et al. (Plant molecular Biology, 35:509-522, 1997) teach that down-regulating the expression of a gene family through antisense method is highly unpredictable. Colliver et al. showed that transformation of bird's foot trefoil with a construct that was antisense to bean chalcone synthase resulted in transformants with increased levels of chalcone synthase transcripts due to increased transcription of other members of the gene family (see page 519 left column paragraph 2, in particular). Furthermore, Bruening (Proc. Natl. Acad. Sci., 95:13349-13351, 1998) teach unpredictability of down-regulating an expression of a gene by sense suppression. The reference teaches that the occurrence of gene silencing by sense suppression may be the unwanted outcome when goal is overexpression, and only few silenced plant lines may appear, and such lines generally will not hold to character when propagated by seed (see the entire article).

In the absence of guidance and unpredictability of the related art as discussed above, undue experimentation would have been required by a skilled artisan to determine how to use sense or antisense cosuppression based approach in reducing the levels of any soybean seed storage protein using a nucleic acid fragment encoding all or a portion of any soybean seed storage protein. See Genentech, Inc. v. Novo Nordisk, A/S, USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that "the

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specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

Claim 24 is directed to food prepared from soybean seeds obtained from a soybean plant comprising in its genome a chimeric gene for reducing the amount of at least one soybean seed storage protein using any method of overexpressing a fragment (sense or antisense orientation with respect to promoter) encoding soybean glycinin or β -conglycinin seed storage protein. The specification provides guidance on making a soybean transgenic plant and its seed which exhibit down-regulation of glycinin or β -conglycinin seed storage proteins by transforming and overexpressing a nucleic acid fragment (sense or antisense orientation with respect to promoter) encoding a portion of said seed storage proteins. But specification does not provide guidance on making soybean seeds with reduced levels of glycinin or β -conglycinin in any manner other than transforming a plant with a chimeric gene comprising sense or antisense overexpression of said nucleic acid fragments. The specification does not provide guidance on co-factors, or positive regulators of glycinin or β -conglycinin for example that makes the glycinin or β -conglycinin gene to overexpress in sense or antisense orientation to produce transgenic soybean seeds with reduced levels of glycinin or β -conglycinin. The specification provides no guidance on up-stream regulatory factors, for example, that may be necessary in stimulating the sense or antisense based suppression of glycinin or β -conglycinin seed storage proteins. In the absence of guidance, undue experimentation would have been required by a skilled artisan to determine how to make soybean seeds with reduced levels of glycinin and /or β -

conglycinin without transforming soybean plant or its seeds with a nucleic acid fragment (sense or antisense orientation with respect to promoter) encoding a portion of said soybean seed storage protein(s).

Given the breadth of the claims, unpredictability of the art and lack of guidance of the specification, as discussed above, undue experimentation would be required by one skilled in the art to make and use the claimed invention. Therefore, it is maintained that the claims are not commensurate in scope with the teachings of the specification.

11. Claims 22-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims are broadly drawn to food prepared from soybean seeds having a reduced quantity of soybean seed storage protein prepared by a method comprising constructing a chimeric gene comprising a promoter operably linked to a nucleic acid fragment encoding all or a portion of a soybean seed storage protein or seed storage protein of any plant species placed in sense or antisense orientation, or wherein said soybean seed storage protein is glycinin or β -conglycinin.

Specification describes transgenic soybean seed embryos transformed with a DNA construct comprising expression of sense or antisense fragments of nucleic acid fragments derived from a nucleotide sequence encoding soybean β -conglycinin. The transgenic soybean embryos exhibited reduced levels of β -conglycinins. No transgenic

soybean embryos or seeds with reduced levels of glycinin using sense or antisense based cosuppression are described. See Examples 1-4.

Claims 22-23 are directed to food prepared by a method of reducing the levels of any soybean seed storage protein using antisense or sense nucleic acid fragment encoding all or a portion of any soybean seed storage protein. The specification does not have adequate written description for the genus of nucleic acid fragments encoding all or a portion of any soybean seed storage protein that would reduce the levels of any soybean seed storage protein under current written description guidelines. Claims encompass large number undisclosed species whose structures and function are unknown. Specification does not describe undisclosed structures of Applicant's broadly claimed genus, and one skilled in the art cannot reliably predict the structures of these species based upon the disclosure of nucleic acid fragments encoding all or a part of glycinin or β -conglycinin.

Furthermore, Applicants have failed to correlate said structures of Applicant's broadly claimed genus to the function of reducing the levels of *any* soybean seed storage protein. Furthermore, Applicants have failed to describe conserved functional elements that are shared by the undisclosed structures of Applicant's broadly claimed genus. The specification does not reduce to practice the broadly claimed genus.

Accordingly, there is lack of adequate description to inform a skilled artisan that applicant was in possession of the claimed invention at the time of filing. See Written Description guidelines published in Federal Register/Vol.66, No. 4/Friday, January 5, 2001/Notices; p. 1099-1111.

Given the claim breadth and lack of guidance as discussed above, the specification does not provide written description of the genus broadly claimed. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time of filing.

Claim Rejections - 35 USC § 102 & 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 22-24 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Trueblood et al. (US Patent No. 4,267,118, issued on May 12, 1981)

Trueblood et al. teach vegetable oil (food) prepared from soybean seeds. See abstract, claims 1-16 and columns 1-5. The food taught in the reference was not made using the same method as the instantly claimed food. However, the instantly claimed food has the same structural limitations as that taught by the reference. Soybean oil as

a food obtained from the claimed method appears to be identical to the soybean oil of the prior art. See *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) which teaches that "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process."

Conclusions

13. Claims 22-24 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vinod Kumar whose telephone number is (571) 272-4445. The examiner can normally be reached on 8.30 a.m. to 5.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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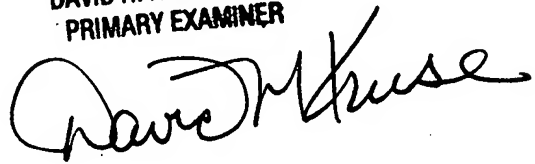
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DAVID H. KRUSE, PH.D.
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read "David H. Kruse", written in a cursive style.